

Office Action Summary	Application No.		Applicant(s)	
	09/847,425		BARBUT, DENISE R.	
	Examiner		Art Unit	
	Paul A Roberts		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 19, 26, 47, 54, and 57 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4-5, 9-10, 12, 19, 26, 47, 53, and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

Election/Restrictions

1. A phone call was made to John Kappos to resolve the applicant's choice for the election of the species on 11/10/03. The applicant elected A1, B2, and C1. Claims readable on that election are claims 1, 3, 6-8, and 11. Claim 1 is generic to claims 2-11. Claims 2, 4-5, 9-10, 12, 19, 26, 47, 53, and 57 are withdrawn from further consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 6-8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parodi US 6423032 in view of St. Germain et al. 2003/0097036. Parodi discloses the method of reversing the blood flow in an artery where the flow of plaque from the ablation moves downstream in the artery. The particular artery claimed, the brachiocephalic artery, is not mentioned, and the method of occluding part of the aorta is not mentioned. St. Germain et al. (Germain) discloses the method of occluding the aorta to increase the blood flow into the cerebral arteries. He discloses that this method can be performed during stenois operations as it lowers the likelihood of the body cerebral area suffering from ischemia. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the Germain and Parodi methods together because the Germain method would decrease the likelihood of ischemia in the cerebral region. As previously mentioned, Parodi's methods are not disclosed to

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be used on the brachiocephalic arteries. Rather, Parodi discloses this technique on the ECA and ICA (see patent for definitions). However, this method could be used on different parts of the vasculature, and the general method of reversing blood flow in cerebral arteries to prevent dangerous plaque deposition in cerebral arteries is well-known in the art. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to use the Parodi method to place the occluding member in the brachiocephalic artery since the Parodi method can be used on cerebral arteries that are capable of having their blood flow reversed. The interventional catheter used in the ECA is an angioplasty catheter.

3. Regarding claim 11, Parodi discloses the use of filter but he does not use filter in the right subclavian artery because the surgical procedure is not being performed near that artery. At the time of the invention it would have been obvious to one having ordinary skill in the art to place filter in the location of the flow of plaque as it is ablated from the vessel; and for a right brachiocephalic artery ablation, that location would be the right subclavian artery.

4. Claims 1, 3, 6-8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. US 6,582,448 in view of St. Germain et al. 2003/0097036. Boyle et al. (Boyle) discloses the method of reversing the blood flow in an artery where the flow of plaque from the ablation moves downstream in the artery. The particular artery claimed, the brachiocephalic artery, is not mentioned, and the method of occluding part of the aorta is not mentioned. St. Germain et al. (Germain) discloses the method of occluding the aorta to increase the blood flow into the cerebral arteries. He discloses that this method can be performed during stenosis operations as it lowers the likelihood of the cerebral area suffering from ischemia. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the

Germain and Boyle methods together because the Germain method would decrease the likelihood of ischemia in the cerebral region. As previously mentioned, Boyle's methods are not disclosed to be used on the brachiocephalic arteries. Rather, Boyle discloses this technique as a general method that can be used on a collateral (carotid artery) blood supply system. The general method of reversing blood flow in cerebral arteries to prevent dangerous plaque deposition in cerebral arteries is well-known in the art. At the time of the invention it would have been obvious to one having ordinary skill in the art to place the occluding member in the brachiocephalic artery and thus place the interventional catheter in the downstream artery such as the ECA since the Boyle method can be used in cerebral arteries that are capable of having their blood flow reversed. The interventional catheter used in the cerebral artery is a stent delivery catheter not an angioplasty catheter. However, it is well-known in the art to use an angioplasty catheter to remove plaque from an artery. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute to the stent deploying catheter of Boyle with an angioplasty catheter because both devices would be capable of successfully removing the plaque from the artery.

5. Regarding claim 11, Boyle discloses the use of filter but he does not use filter in the right subclavian artery because the surgical procedure is not being performed near that artery. At the time of the invention it would have been obvious to one having ordinary skill in the art to place filter in the location of the flow of plaque as it is ablated from the vessel; and for a right brachiocephalic artery ablation, that location would be the right subclavian artery.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
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12/01/03



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